Masarykův onkologický ústav

Conducting clinical trials at the Masaryk Memorial Cancer Institute

Information for CROs and sponsors

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A healthcare provider accredited by the Organization of European Cancer Institutes (OECI) and the Czech Society for Healthcare Accreditation

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Introduction

Our aim is to provide sponsors and CROs with professional, transparent and efficient collaboration, enabling the rapid initiation of trials, high-quality patient recruitment and the safe conduct of clinical trials. The main point of contact for collaboration is **the Clinical Trials Department at the Masaryk Memorial Cancer Institute**.

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Overview and facilities of the centre

The Masaryk Memorial Cancer Institute is the largest specialised cancer centre in the Czech Republic. Within a single institution, we provide highly specialised diagnostic, therapeutic, research and educational services in the field of the prevention and treatment of solid tumours.

The MOÚ is an organisation directly managed by **the Ministry of Health of the Czech Republic** and also acts as the main coordinator of oncology care for the South Moravian Region. In collaboration with Brno University Hospital and St. Anne's University Hospital, it has been granted the status of a National Cancer Centre. The centre's international standing is confirmed by its membership in the European reference networks **EURACAN** and **GENTURIS**. The MOÚ is also the only comprehensive cancer centre in the Czech Republic accredited by the **Organisation of European Cancer Institutes (OECI)**.

In the field of clinical trials, we focus on **the evaluation of drugs in phases I to III** in adult patients with solid tumours. Our centre also includes a specialised Early Phase Trial unit (https://www.mou.cz/en/early-phase-trial-unit/t1919), which is **certified by the State Institute for Drug Control (SÚKL) to conduct first-in-human studies**. Each year, we initiate approximately 15 to 25 new clinical trials of medicinal products and other types of clinical studies, including a large number of academic projects.

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Characteristics and facilities of the centre

A multidisciplinary team is involved in the conduct of clinical trials, typically comprising the Comprehensive Cancer Care Clinic, the Clinical Trials Department, the Hospital Pharmacy, the Radiology Department, the Nuclear Medicine Department, the Laboratory Medicine Department and the Department of Oncological Pathology. For examinations that cannot be carried out in-house, we collaborate with external healthcare facilities.

List **of examinations not available at MOÚ:**

- Ophthalmological examinations – *a separate contract is required between the client and the ophthalmology department – (we prefer Oftalpro)*
- DEXA – *a separate contract is required between the client and the DEXA facility*
- Audiometry *(Brno University Hospital)*
- Certain laboratory tests: HIV-1 antibody, HIV-1/2 antibody, HIV-2 antibody, HBcAb, HBV DNA test, HCV RNA test, Immunoglobulin IgE, tryptase, Anti-nuclear antibody (ANA), anti-double-stranded deoxyribonucleic acid (dsDNA), circulating anti-neutrophil cytoplasmic antibody (cANCA), perinuclear anti-neutrophil cytoplasmic antibody (pANCA), Troponin I, CK-M *(FNUSA/Brno University Hospital, based on a cooperation agreement between the Masaryk Memorial Cancer Institute and the University Hospital)*

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Quality Management

The conduct of clinical trials at MOÚ is governed by Internal Guideline 2/2018 regulating clinical research and an extensive set of standard operating procedures covering all phases of clinical trials – from study selection to the archiving of documentation.

Compliance with these procedures is systematically monitored. Several internal and external audits are conducted at MOÚ each year. The department has also undergone several inspections by the State Institute for Drug Control and an FDA inspection (2012), during which no critical findings were identified. We provide quality management documents to sponsors upon request.

List of SOPs for clinical trials:

I-A1	Creation and updating of SOPs	II-D1	Communication and education within the clinical trial	II-E4	Compensation for patients in clinical trials
I-A2	Staff training on SOPs	II-D2	Initiation visit	II-E5	Adverse and serious adverse events
I-A3	Employee training on KH	II-D3	Monitoring visit	II-E6	Collection, processing, storage and dispatch of biological samples
I-A4	Quality control and monitoring – MOÚ as a KH centre	II-D4	Screening	II-E7	ECG
I-A5	Controlled documentation	II-D5	Randomisation	II-E8	Measurement of physiological functions in hospital patients
I-A6	Legislation for clinical trials and GCP	II-D6	Blinding and unblinding of the subject	II-F2	Clinical trial data management and patient record sheets
I-A7	Document storage and management on OKS	II-D7	The medicinal product under evaluation	II-F4	Note: STUDIES in NIS
I-B2	OKS Human Resources Management	II-D8	Clinical trials unit	II-F5	Source documentation
I-B3	Project Manager	II-D9	Clinical trials and NIS SONIS	II-F6	Quality assurance of instruments and laboratory procedures in KH
I-B4	Start-up Coordinator	II-D10	Protocol deviations	II-F7	Evaluation of laboratory deviations
I-B5	Study Coordinator	II-D11	Delegation of activities in clinical trials	II-G1	Termination of clinical trials and archiving
I-B6	Data Manager	II-D12	Supervision by the principal investigator within the clinic	J1	Organisation and staffing of early-phase clinical trials
I-B7	Payments for KH	II-E1	Patient selection and enrolment in a clinical trial	J2	Facilities and equipment within the KH early-stage programme
I-B9	Student nurse	II-E2	Informed consent	J3	Ensuring the safety of trial subjects in early-phase clinical trials
II-C1	Selection of clinical trials	II-E3	The course of a patient's participation in a clinical trial	N-1	Ensuring standard care for study patients at NLZP (Memo to File)
II-C2	Procedures prior to the commencement of a clinical trial				

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Feasibility

All clinical trial proposals are accepted exclusively by the Clinical Trials Department. Centralising this process enables effective assessment of the study's feasibility and coordination across individual clinical sites.

If **a Confidentiality Agreement (CDA)** needs to be concluded before submitting more detailed documentation, we normally accept only the 'PI-only' version issued in the name of **doc. MUDr. Radka Lordick Obermannová** (Head of the Clinical Trials Department), ideally in 'wet-ink' form. The final nomination of the principal investigator takes place only after the study's feasibility has been assessed.

When assessing feasibility, we take into account, in particular, the medical and scientific value of the study, the nature of the investigational medicinal product, the availability of a suitable patient population, the existence of competing studies, and previous experience with the sponsor or CRO. For a qualified assessment, it is essential to provide at least a synopsis of the clinical trial.

We greatly appreciate feedback on every study proposal, including cases where the study is not allocated to the Czech Republic. This information is important for planning our centre's capacity.

Contact:

feasibility@mou.cz

Site Selection Visit (SSV)

The screening visit is organised through the Clinical Trials Department and represents a key step in deciding whether to include the centre in the trial. The principal investigator is nominated by the management of the relevant clinic, and we guarantee that this role is performed by an experienced doctor with the appropriate qualifications and experience in clinical research.

We prefer a face-to-face screening visit, which allows for a detailed presentation of the centre's organisational and technical facilities (technical facilities available on request in advance). A teleconference is also possible. Prior to the visit, we request that the study protocol be sent to us in both electronic and printed form (2 A4 copies). In exceptional cases, the selection visit may also be conducted on the basis of a draft protocol.

We expect representatives of the sponsor or CRO to have a good understanding of the study, its organisational aspects and the timeline.

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Start-up phase

The start-up phase begins with the confirmation of the centre's selection and ends with the study initiation visit. During this phase, intensive preparation for the study takes place, involving a range of specialists – lawyers, economists, study coordinators and healthcare staff.

Open communication and timely notification of any changes to the study are essential for the smooth running of this phase. During the start-up phase, a complete study team is assembled, which usually includes:

Roles	Responsibilities/agenda
Principal Investigator	IWRS, CRF, SUSAR
Co-investigators (2–6)	1 SI - CRF
Study coordinator (medical background)	IWRS, CRF, SUSAR, laboratories, questionnaires, image recording, ECG, etc.
Study nurse (1–4 on the Delegation Log, others as standard in the Memo to File)	Sometimes central laboratories
Data manager (1)	CRF, SAE, queries
Laboratory technician (1 on the Delegation Log, others on the list)	n/a
Radiologist (2)	n/a
Pharmacist (2)	IWRS
Pathologist (1 on the Delegation Log, others on the list)	n/a
Internal medicine specialist – cardiologist (1 on the Delegation Log, others on the list)	n/a

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Start-up phase

We generally provide study team documentation for the entire team at the same time. We prefer the newly required site suitability document within the CTIS to be completed by the sponsor based on information from the site visit. The document is signed by the principal investigator.

Part of the study preparation also involves the sponsor/CRO providing the following study materials **prior to the SIV**:

Document	Form
Current version of the protocol	electronic and 3 printed copies, A4 format
Czech synopsis	electronic
Sample ICF	electronic
Laboratory manual	electronic and 2 colour-printed copies
Other manuals	electronic
Start-up questionnaire	electronic
Pharmacy questionnaire	electronic
Investigator Site File	paper
Laboratory kits or other equipment (tablets, etc.)	physical

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Contract and Budget

The MOÚ enters into a single tripartite contract exclusively. A standardised contract template enables transparent study management and administrative efficiency. To expedite the approval process, we prefer to use standardised contract templates, in particular the national template recommended by the Ministry of Health.

Both the contract and the budget are assessed by a multidisciplinary team – the principal investigator, the legal department, the finance department, the hospital pharmacy and the Clinical Trials Department. You will receive an initial response within approximately 8 weeks. We are able to provide comments on the budget within a shorter timeframe. We accept electronic signatures on contracts (not DocuSign on our part).

All funds are paid exclusively by MOÚ, which subsequently ensures their allocation in accordance with internal rules. The budget should be structured as simply as possible, ideally with the maximum number of procedures included in individual study visits.

In providing our comments, we adhere to a non-public internal price list for clinical trials.

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Contract and quote

Excerpt from the price list – start-up fees:

Start-up fee – payable upon signing the contract with no further conditions – CZK 40,000

Pharmacy start-up fee – payable upon signing the contract with no further conditions – CZK 8,000–10,000

Archiving fee (25 years) – CZK 35,000

Contract amendment fee – CZK 5,000

Fee for the use of complex systems requested by the CRO/client – e.g. SIP: CZK 20,000

Flat-rate fee for each unsuccessful screening – CZK 8,000

Flat-rate fee for each unscheduled visit – CZK 6,000

Contract and quote

Masarykův onkologický ústav

Poskytovatel zdravotních služeb akreditovaný Organizací evropských onkologických ústavů (OECI) a Českou společností pro akreditaci ve zdravotnictví.

Statement on internal price list for clinical trials

We confirm the following items are according to the internal site price list for clinical trials:

Budget item	Price	Comment
Start-up Fee	40.000 CZK	To be paid after CTA signature
Document and archiving Fee (25 years)	35.000 CZK	To be paid after CTA signature
Pharmacy Start-up Fee	10.000 CZK	To be paid after CTA signature
CTA Amendment Fee	5.000 CZK	To be paid after CTA Amendment signature
Screen Failure Flat Fee	8.000 CZK	We require all SF to be paid at the flat fee (does not include biopsy and radiology procedures)
Unscheduled Visit Flat Fee	6.000 CZK	Per each UNSCH visit (does not include biopsy and radiology procedures)
Pharmacy Fee – i.v. therapy	2.500 CZK	Per 1 infusion
Pharmacy Fee – p.o. therapy	1.500 CZK	Per 1 patient/1 month on the therapy
Pharmacy Complex Fee	2.500 CZK	Per 1 month/study – since first IMP shipment, includes storage, preparation, accountability, destruction – if needed locally
Central Lab Complex Free – level 1	1.352 CZK	Applicable for visit with 1 sampling timepoint (includes sampling, processing, shipping, administration)
Central Lab Complex Free – level 2	2.354 CZK	Applicable for visit with multiple sampling timepoint or post infusion sampling (includes sampling, processing, shipping, administration)
Central Lab Complex Free – level 3	4.358 CZK	Applicable for visit with demanding sampling requirements (timed sampling for studies phase 1 or 2) (includes sampling, processing, shipping, administration)
Central Lab Complex Free – level 4	6.362 CZK	Applicable for first-in human trials, visits with high-level sampling with special requirements for processing (outside working hours etc.) (includes sampling, processing, shipping, administration)
Response Evaluation Criteria (RECIST)	2.500 CZK	Per 1 radiology assessment
Archived Tumor Sample	2.500 CZK	Preparation, handling, shipping and submission of tumor-related samples to central lab

All prices include overhead.
VAT is not included.

We provide certain other charges from the price list in the form of a statement; see the left-hand side:

In the area of patient compensation, we prefer cash payments at the MOÚ cash desk or the use of payment vendors to transfer compensation to the patient's account. In the case of cash payments, we require a deposit (of CZK 30,000–50,000), which is used to ensure the smooth payment of compensation to patients. Travel expenses are documented in the patient's file and are available to the monitor during the monitoring visit.

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Site Initiation Visit (SIV)

The date of the initiation visit is scheduled by the study coordinator in collaboration with the principal investigator and the study monitor. The visit is organised at a time when the study is expected to commence within 4–6 weeks.

The site initiation visit usually takes place over one working day, between 8 am and 3 pm, at the Clinical Trials Department. The study coordinator prepares the visit schedule and shares it with the study team and the study monitor. From this point onwards, the study coordinator becomes the centre's main point of contact for both the monitor and the sponsor.

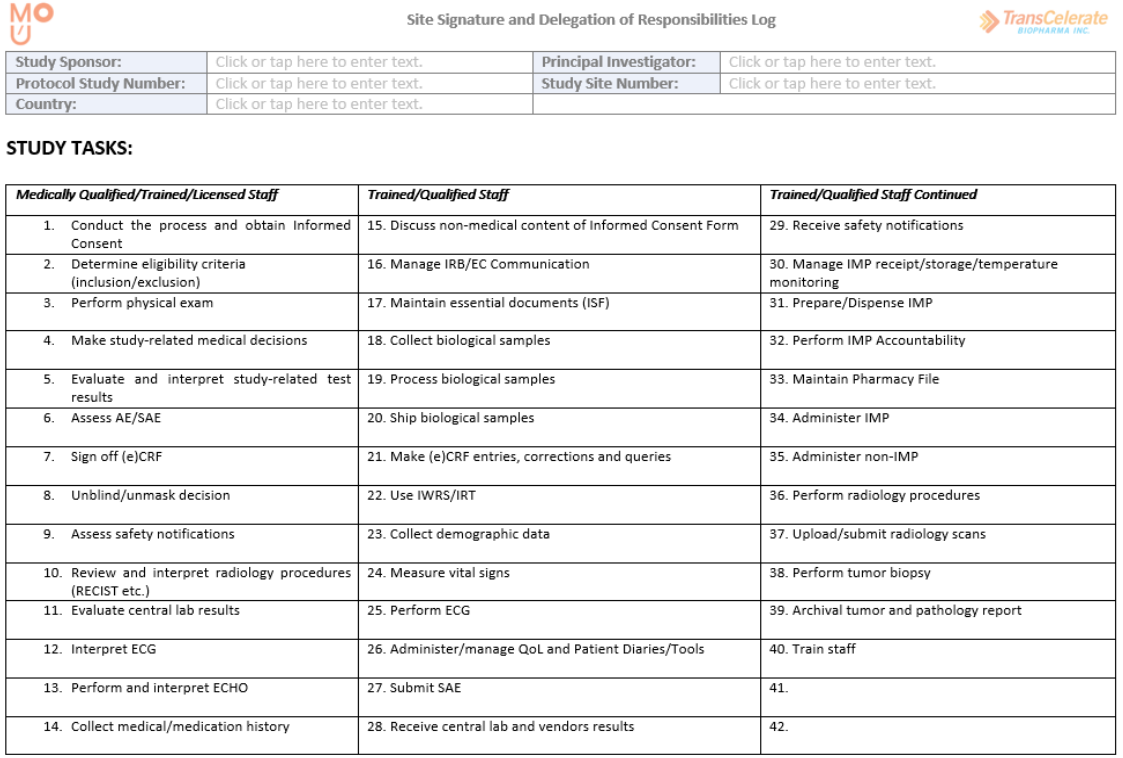
The prerequisites for conducting the initiation visit are regulatory approval of the study, completion of the contractual process (the contract is either signed or at least finalised), and delivery of all required study materials. A key component of the initiation visit is also the training of the study team, the finalisation of the delegation of responsibilities, and a review of the Investigator Site File documentation.

During the initiation visit, we require the delivery of the Investigator Site Files, including (double-sided) printed informed consent forms, in sufficient numbers at the start of the clinical trial and subsequently (additional copies, new versions, etc.). The CRO/sponsor is responsible for ensuring that fully approved informed consent forms are delivered to the centre.

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Site Inspection Visit (SIV)

Please be advised that **we only accept the Delegation Log on the MOÚ form**, which is required in accordance with SOP II-D11 and the SÚKL recommendation. This is a document for the principal investigator and the centre. We complete the Delegation Log prior to the SIV; during the SIV, it is simply supplemented with the signatures and initials of the study team, and the signature and date of the principal investigator. Other DL templates are not accepted.



Site Signature and Delegation of Responsibilities Log

Study Sponsor:	Click or tap here to enter text.	**Principal Investigator:**	Click or tap here to enter text.
Protocol Study Number:	Click or tap here to enter text.	**Study Site Number:**	Click or tap here to enter text.
Country:	Click or tap here to enter text.		

STUDY TASKS:

Medically Qualified/Trained/Licensed Staff	*Trained/Qualified Staff*	*Trained/Qualified Staff Continued*
1. Conduct the process and obtain Informed Consent	15. Discuss non-medical content of Informed Consent Form	29. Receive safety notifications
2. Determine eligibility criteria (inclusion/exclusion)	16. Manage IRB/EC Communication	30. Manage IMP receipt/storage/temperature monitoring
3. Perform physical exam	17. Maintain essential documents (ISF)	31. Prepare/Dispense IMP
4. Make study-related medical decisions	18. Collect biological samples	32. Perform IMP Accountability
5. Evaluate and interpret study-related test results	19. Process biological samples	33. Maintain Pharmacy File
6. Assess AE/SAE	20. Ship biological samples	34. Administer IMP
7. Sign off (e)CRF	21. Make (e)CRF entries, corrections and queries	35. Administer non-IMP
8. Unblind/unmask decision	22. Use IWRS/IRT	36. Perform radiology procedures
9. Assess safety notifications	23. Collect demographic data	37. Upload/submit radiology scans
10. Review and interpret radiology procedures (RECIST etc.)	24. Measure vital signs	38. Perform tumor biopsy
11. Evaluate central lab results	25. Perform ECG	39. Archival tumor and pathology report
12. Interpret ECG	26. Administer/manage QoL and Patient Diaries/Tools	40. Train staff
13. Perform and interpret ECHO	27. Submit SAE	41.
14. Collect medical/medication history	28. Receive central lab and vendors results	42.

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Clinical trial monitoring

Clinical trial monitoring takes place in dedicated premises at the Masaryk Memorial Cancer Institute. The organisation of monitoring visits is coordinated by the study coordinator, who ensures the availability of documentation and the cooperation of the study team. The date must be arranged well in advance, at least 3 weeks. In the case of a monitoring visit arranged solely at the pharmacy (e.g. unblinded monitor), the date of the monitoring visit must be arranged in the same manner as described above. Such visits usually take place after 1 pm.

Monitoring visits must be planned well in advance. Monitoring of commercial clinical trials at MOÚ takes place on the 2nd floor of the newly opened pavilion on Vaňkovo náměstí. The maximum capacity is 4 monitoring slots per day. If the attendance of more than one person (2) is absolutely necessary – e.g. when handing over a study – it is necessary to book 2 monitoring slots. In accordance with the clinical trial contract, monitoring of clinical trials takes place during normal working hours, **namely Monday to Friday from 7.00 am to 3.30 pm. After these hours**, **it is not permitted to remain on the premises without the presence of a MOÚ employee**, due to the need to secure the premises and to ensure stricter control of access to personal data.

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Clinical trial monitoring

The list of patients scheduled for inspection must be sent at least one working day prior to the visit. The monitor or auditor has full rights to inspect medical records for the purpose of monitoring the conduct of the clinical trial. However, in accordance with Act No. 372/2011 Coll. on Health Services, Section 66(6), there is an obligation to make a record of every inspection (who inspected the records and for what purpose) and to file this record in the patient's medical record. Work with medical records is subject to strict data protection rules and legislative requirements. It is strictly forbidden to make any permanent alterations to medical records; please use removable sticky notes for communication with the study team. Medical records must always be returned to their original state (do not leave sheets loose outside the folders).

We strive to cooperate as closely as possible with the monitors. At the same time, we expect them to be available in the event of urgent queries regarding patient safety or the conduct of the study.

Payments

Compliance with contractual payment terms is essential for the smooth running of clinical trials. As a state-run healthcare facility, we are obliged to follow legislative regulations, including the imposition of penalties for late payments. In the event of non-compliance by the CRO, we will also inform the study sponsor.

To ensure a smooth invoicing process, it is important to submit supporting documents by the agreed deadlines, correctly reference payments with the invoice number, and maintain active communication when resolving any discrepancies. It is also very helpful to designate a specific contact person responsible for the study's financial matters.

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Contact details

Up-to-date information on clinical trials and contact details can be found on the MOÚ website. The Clinical Trials Department is ready to provide support at every stage of the collaboration – from feasibility to the conclusion of the trial.

www.mou.cz/en/

https://www.mou.cz/klinicke-studie/t1520

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Masarykův onkologický ústav

Conclusion

Our aim is to build long-term partnerships with clinical trial sponsors and CROs. We strive to ensure that collaboration with MOÚ is professional, effective and contributes to the development of modern cancer treatment. Thank you for your trust and cooperation.

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